PUBLIC-PRIVATE PARTNERSHIP PROGRAM

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MESSAGE FROM THE DIRECTOR

Dr. Barbara B. Mittleman, Director, NIH Public-Private Partnership Program, National Institutes of Health

Welcome back from the summer of 2011. Recent months have held lots of changes in the world around us, with continued economic pressures and deficit reduction plans in development, ongoing efforts on many fronts to make drug development more successful and efficient, as well as exciting progress in scientific discovery. How to translate that discovery to improvements in public health continues to be a focus of active discussion and activity, both inside the National Institutes of Health (NIH) and in academia and industry. So how does the NIH Public-Private Partnership (PPP) Program participate in such discussions and efforts?

Crowdsourcing can deliver solutions, offer economies of time and money, and engage a community of diverse problem solvers who may not have applied their skills and insights to questions of importance in biomedical science. New technologies such as mobile devices allow for real-time monitoring of human behavior and status and environmental factors and offer a chance for intervention on an individual basis when and where there is need. Sharing of data and data analysis tools provides an opportunity to wring additional value from existing data sets and to seek connections not anticipated at the time of initial data collection. And biomarkers offer the opportunity to customize treatment and to develop companion diagnostics, furthering efforts to prevent, treat, and reduce the burden of disease.

So what do crowdsourcing, mobile devices, data platforms, and biomarkers all have in common? One common theme is intellectual property (IP)—in other words, questions about who owns and controls the value generated by these activities and who gets to collect the benefits. Articles in this fall 2011 newsletter address and describe the activities in each of these realms: the recent crowdsourcing meeting convened by the National Center for Research Resources; the upcoming third mHealth Summit convened by the Foundation for the NIH; efforts to leverage an information technology tool developed by Johnson & Johnson on a backbone of open-source software whose development was funded by NIH (i2b2, Informatics for Integrating Biology and the Bedside, an NIH-funded National Center for Biomedical Computing based at Partners HealthCare System); and PPPs and recent PPP activity at NIH, penned by Agnes Rooke. Agnes was recently on detail in the PPP Program from her duties at the National Institute of Allergy and Infectious Diseases' Office of Technology Transfer. We'll miss her and know she has learned lots about PPPs to take back to her home office.

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SPOTLIGHT

In this issue of the National Institutes of Health (NIH) *PPP Advisor* we bring you news of several exciting programs and activities currently under way—Biovigilance, mHealth (mobile health), *tran*SMART, and Crowdsourcing:

- Biovigilance - **Dr. Jerry Holmberg,** Senior Advisor for Blood Policy, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, offers information about biovigilance, the challenges and partnership opportunities, as well as information about the first Federal biovigilance workshop, recently held on June 3, 2011.
- mHealth - Following on the broad interest in the use of mobile technologies for health, we have news from **Dr. Bill Riley** of the National Heart, Lung, and Blood Institute about the NIH mHealth Inter-Institute Interest Group as well as a guest feature article by **Mr. Richard Scarfo,** Director of Marketing, Communications and Strategic Alliances, Foundation for the National Institutes of Health and Director, mHealth Summit. Mr. Scarfo provides information on the upcoming 2011 mHealth (mobile health) Summit.

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Looking forward, the presentations in this year's PPP Coordinating Committee series will address the nuances of IP and its disposition and will explore the notion of precompetitive space. If precompetitive activities generate resources that are widely available for use, what is the best way to accomplish developing and sharing such precompetitive resources? These questions and others will inform PPP activities and efforts in the coming 2011-2012 year.

We look forward to your joining with us in these explorations, and as always, we are available to help you think through and develop PPPs in support of NIH's research and public health missions. Welcome back! ❖

"Recent months have held lots of changes in the world around us...as well as exciting progress in scientific discovery. How to translate that discovery to improvements in public health continues to be a focus of active discussion and activity."

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- *tran*SMART - This spring, the NIH Public Private Partnership (PPP) Program office and other members of the *tran*SMART Organizing Committee hosted the *tran*SMART Consortium Design meeting. One of the *tran*SMART organizing committee members, **Dr. Eric D. Perakslis**, Vice President, Research & Development IT, Johnson and Johnson Pharmaceutical Research and Development, provides an overview of the developing *tran*SMART Consortium.
- Crowdsourcing - **Dr. Olga Brazhnik**, Division of Biomedical Technology, National Center for Research Resources (NCRR), NIH, provides lots of exciting information about open innovation and the recent crowdsourcing meeting sponsored by the NCRR and held at the NIH on July 18, 2011. Her article provides an overview of crowdsourcing and prizes as well as approaches and opportunities for partnering.

We are very excited to include in this issue an article penned by another NIH staff member, Ms. Agnes B. Rooke, Technology Development and Transfer Associate, Inventions and Agreements Branch, Office of Technology Development, National Institute of Allergy and Infectious Diseases (NIAID). Ms. Rooke, who was on detail to the PPP Program from the NIAID, provides her impressions regarding the importance of partnerships, PPP activity at the NIH, and PPP Program activities. ❖

BIOVIGILANCE: *VIGILANCE AND SURVEILLANCE OF TRANSFUSED OR TRANSPLANTED BIOLOGICAL PRODUCTS*

Jerry A. Holmberg, Ph.D., Senior Advisor for Blood Policy, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Advances in science and health care technology have led to more biologic products being collected in order to sustain and improve the quality of human life. In the US in 2008, over 23 million units of blood or blood products, 28,000 organs, and two million tissue allografts were transfused or transplanted.

Despite these large numbers, demand often exceeds availability, particularly for organs. Challenges exist to monitor and ensure appropriate access to safe products, both in the domestic and global arenas. Efforts to increase the availability of these products also may increase the opportunities for transmission of infectious pathogens, including viruses, bacteria, parasites, and prions. These risks are multiplied when there are multiple recipients from a common donor.

The term "biovigilance" extends beyond blood (a.k.a. hemovigilance) to incorporate the monitoring of reactions/events associated with tissues, organs and cellular components. The Office of the Assistant Secretary for Health (OASH) views vigilant surveillance for the safety of blood, cells, tissues, and organs as critical to informed policy decisions, health care quality improvement, and the prevention of infectious diseases with the goal of improving patient outcome and maintaining living donor health. Last fall, the Office of the Assistant Secretary for Health started work on developing the foundational elements and operating framework for a National Biovigilance Program and a public-private partnership (PPP).

Human errors and process errors including equipment or supply defects can compromise living donor health and the biologic outcome in patients. There can also be unknown causes of adverse outcomes, such as with emerging infectious diseases. Being vigilant to monitor, detect, and analyze available data is essential for an effective biovigilance program.

Biovigilance stakeholders include both the public and private sectors. The public sector includes all levels of government (Federal, state, local, territorial, and tribal). Within the Federal government there are not only the Health and Human Services

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(HHS) agencies but also other cabinet-level Departments such as Defense, Veterans Affairs, and Commerce. In the private sector, stakeholders include professional organizations, accreditation organizations, payers, pharmacia, and biomedical and research facilities (private or public) as well as managing partners. Governance or management of stakeholder interaction is important to the Federal government to ensure balance and preserve trust extended by the public.

On June 3, 2011 OASH hosted the first Federal-sector workshop on biovigilance with the assistance of the NIH PPP Program. Over sixty Federal employees were in attendance. The outcome of this meeting was successful not only in obtaining clarity and paths forward but also developing relationships across the Federal sector.

Additionally, OASH recently investigated a means to achieve stakeholder involvement through a proposed PPP. Although there are many opportunities created by a public-private venture, there is also a need for a clear pathway for long-term governance, funding for sustainability, and clarity on data collection, analysis, and dissemination to improve practice. This spring a request for information (RFI) was posted in the *Federal Register* to solicit responses from all potential stakeholders. Responses from the various stakeholders expressed that, while a PPP is supported, there are unique needs of blood, cells, tissues, and organs that may be addressed in unique microcosms of the overall biovigilance PPP.

A comprehensive biovigilance program should bridge both regulatory and organizational gaps to address not only patient safety and donor health issues but also public health concerns. Regular assessment and evaluation of data are expected to enable informed decision-making both in the public and private sectors, including reevaluation of current policies and effectiveness to reduce risks while balancing availability of life saving biological products. A well-designed PPP is envisioned to facilitate science and technology to advance transfusion and transplantation as research questions are addressed from the data obtained. A well-defined transparent governance of a PPP for biovigilance is thought to be in the best interest of the donor and the patient. ❖

Mobile Health Technologies and the NIH

William T. Riley, Ph.D., Program Director, Clinical Applications and Prevention Branch, National Heart, Lung, and Blood Institute, and Chair, NIH mHealth Inter-Institute Interest Group

The mobile communication and computing revolution is well under way and is changing the delivery of many services, including health care. The increasing penetration rates of mobile phones are staggering. According to the latest data from the Pew Research Center's Internet & American Life Project, 83% of Americans own a cell phone of some kind, and over a third use or own a smartphone. These devices are changing not only the ways that people communicate but also the way that people access data. The digital divide of poor vs. rich Internet users is being bridged by smartphones, which offer low-socioeconomic-status users access to the Internet at a lower cost than traditional personal computer broadband access. In developing countries, mobile phones allow people to leapfrog landline infrastructure and provide voice and data connectivity to users in rural and secluded areas.

The mobile revolution holds considerable promise for improving health care. Mobile and wireless technologies make it possible to assess and intervene preemptively wherever the patient is. Via a growing variety of wireless sensor technologies, the biomedical, behavioral, and environmental states of a person can be monitored longitudinally. Advanced analytics allow us to learn from these rich patterns of patient data and better detect and distinguish a health care signal from noise. An intervention can be delivered in response to patient data interactively and immediately when the patient needs it, and some of the more mundane or routine treatment adjustments and interventions can be automated, reserving labor-intensive and expensive clinical contacts for more complex clinical presentations. Perhaps most importantly, mobile and wireless health applications give people more control over their own health, with an array of preventive health assistance, regular feedback on health status, and the ability to better manage chronic conditions.

So what's so new about mobile health or mHealth? We've had telemedicine and telehealth efforts since the days of landline telephones, and the Internet has greatly increased telemedicine capabilities, while also giving users interactive tools to better manage their health. Is mHealth really any different from eHealth? mHealth is in many ways an extension of eHealth, and as smartphone penetration increases, the distinction between health applications by phone vs. those on the Web will diminish. There are a number of advantages to mHealth compared with the Internet and other more

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traditional communication technologies for improving health care.

To understand the advantages, it is helpful first to define what mHealth is. mHealth refers to health applications delivered on wireless computer devices that are intended to be "always on and on the person throughout the day." Mobile phones are the prototypic mHealth devices, but body sensor networks and a range of sensors worn on, or in, the body that wirelessly transmit data throughout the day also are part of the mHealth armamentarium. It is this ability to assess and intervene throughout the day that makes mHealth qualitatively different from eHealth. An Internet health application is only useful if the user is motivated to log on to the site, enter data, and utilize the information provided. Email reminders to log on to the site are helpful, but only if the user checks email regularly. In contrast, automated and wireless sensors generate and transmit data 24/7 even if the patient does nothing. For inputs requiring patient effort, recording reminders interrupt the patient's daily routine, and the action of inputting data can be confirmed in real time. Experience sampling or ecological momentary assessment methodologies have used this "real-time intrusiveness" to perform random samples of patient experiences since the advent of personal data assistants.

The advantage of being always on and on the person is critical to outputs as well as to inputs. Not only can individuals be monitored 24/7 in their natural or free-living environments, but also health information, persuasion, medical instructions, behavioral skills, incentives, and an array of other health care interventions and strategies can be delivered whenever and wherever. This capability allows mHealth applications to intervene in the context of behavior in a person's daily routine and at the time the individual most needs the intervention. The potential of adaptive interventions becomes nearly limitless via mHealth. For example, based on accelerometer data (from accelerometers worn by an individual or resident on the mobile phone) and GPS (Global Positioning System) data, an mHealth system to encourage physical activity and prevent long periods of sedentary behavior can monitor physical activity in real time throughout the day. Based on these data, the system can encourage the user to become more physically active after periods of inactivity; suggest appropriate physical activities based on user preferences, time of day, location, and weather; and subsequently reinforce engaging in physical activity via text message, contacting a significant other to report on the user's progress, and even giving monetary credit on an mBanking application. And with advanced analytics, the system can learn over time which interventions at which times seem to work better and further adapt to better personalize the program.

The combination of real-time monitoring and advanced analytics also provides the ability to offload more of the health care interventions that currently require considerable health care professional time and expense. Treatment adjustment algorithms can be automated so that the more routine adjustments do not require the input of a health care professional. Alerts to health care professionals could be reserved for when patient data are beyond the scope of the automated algorithm's adjustment capabilities. As a result, time spent by health care professionals on routine treatment decisions can be minimized, and more time can be spent on more complicated presentations. Automated treatment adjustments, however, require considerable safety and efficacy data to ensure that they work properly. The U.S. Food and Drug Administration (FDA) has already approved a number of mHealth applications including consumer-friendly blood pressure cuffs that monitor and store blood pressure via smartphone, GE's Pocket Viewer, and Airstrip Technologies' Airstrip. The FDA recently released draft guidance for public comment on mHealth applications to address these automated treatment adjustment programs and numerous other medical applications of mobile technologies (see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm).

So if private industry is developing innovative wireless and mobile applications and the FDA is actively regulating this industry to ensure that the applications are safe and effective, what is the role of the National Institutes of Health (NIH)? mHealth technologies have greatly outpaced the research needed to evaluate them, and mHealth applications that are not making a medical claim do not need FDA approval. As a result, numerous mHealth applications are commercially available, but they lack research support or were not developed in an empirically based manner. Therefore, one critical role of the NIH is to support research that evaluates the validity and efficacy of these mobile applications. The NIH currently supports approximately 100 grants to develop and/or evaluate mobile technologies applied to health, but more needs to be done. With the current timeline from grant submission to the completion and publication of a randomized clinical trial, many of the mHealth applications currently being published and reported on are already dated or obsolete. For example, the iPhone has been commercially available for approximately 4 years, so any NIH-supported researcher completing a typical 5-year R01 (standard NIH research project grant) project would not have used an iPhone application. To address this difference in the pace of technology and research, the NIH, in partnership with the National Science Foundation,

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the McKeeson Foundation, and the Robert Wood Johnson Foundation, recently held a meeting of methodologists, biostatisticians, engineers, and mHealth researchers to consider ways to streamline the research process to better keep pace with the technology. More information, including upcoming releases of findings from the meeting, can be found at http://obssr.od.nih.gov/scientific_areas/methodology/mhealth/mhealth-workshop.aspx.

This is but one of a number of efforts at the NIH to foster research in this rapidly evolving area of mobile technologies applied to health. mHealth advancements also provide important new tools for research that the NIH will need to support. One recent industry example of leveraging mHealth advancements in research is the Pfizer REMOTE study, which is evaluating a medication for overactive bladder using remote electronic data collection only, allowing them to enroll patients regardless of their geographic proximity to clinical sites. The NIH is playing a growing role in the development of mHealth research tools that make this sort of remote monitoring study possible.

To facilitate mHealth efforts at the NIH, the NIH mHealth Inter-Institute Interest Group (mHealth IIIG) was formed almost two years ago. The NIH mHealth IIIG is coordinated from the NIH Public-Private Partnership (PPP) Program in the Office of Science Policy, Office of the Director, NIH, and consists of over 100 members from various NIH Institutes, Centers, and Offices. In addition to sharing mHealth research support efforts across the NIH, the NIH mHealth IIIG also develops trans-NIH initiatives and coordinates workshops and training efforts. One of the major efforts of the mHealth IIIG has been coordinating the research track for the mHealth Summit, both last year and this year. The Summit, led by the Foundation for the NIH (FNIH), with NIH as an organizing partner, brings together health research, policy, business, and technology in the mHealth space, and the mHealth IIIG has reviewed the abstract submissions and developed the program for the Summit. At this year's mHealth Summit, the NIH, with support from the FNIH and other Summit partners, will offer a winter version of the successful mHealth Summer Training Institute. This Institute, led by the NIH Office of Behavioral and Social Sciences Research, brings together early-stage biomedical researchers, behavioral researchers, engineers, and computer scientists to advance mHealth research. More on the mHealth Summit is available at http://www.mhealthsummit.org/.

This is a period of exciting, rapid evolution in mHealth. Mobile technologies applied to health offer the potential for improved health at reduced cost, but for this potential to be realized, the advances in technology must be matched with advances in research. To realize the potential for mHealth, rigorous development based on empirical support and clinical need, along with rigorous evaluation to validate that these technologies improve health and/or reduce cost, must be encouraged and supported. The NIH is uniquely positioned to encourage and support mHealth research and to partner with private industry, nonprofit organizations, and sister agencies within the Federal government to ensure that these mobile health technological innovations get the research scrutiny they need. ❖

2011 mHealth Summit Returns With a Focus on "Shaping the Future of Mobile Health"

Mr. Richard Scarfo, Director of Marketing, Communications, and Strategic Alliances, Foundation for the National Institutes of Health, and Director, mHealth Summit

In just three short years, the mHealth Summit has grown into the largest mobile health event in the United States. Tagged by industry as the "the global convener of the mHealth ecosystem," the event continues to attract leaders from across key sectors of government, industry, academia, providers, technology innovation, not-for-profit organizations, and the private sector. The event has remained firm in its goal of advancing collaboration in the use of wireless technologies to improve health outcomes across the globe and is a testament to the convening power of the Foundation for the National Institutes of Health (FNIH).

The FNIH is again hosting the event this year in partnership with the National Institutes of Health (NIH), the mHealth Alliance, and new organizing partner, the Healthcare Information and Management Systems Society. The Summit takes place **December 5-7, 2011, at the Gaylord National Resort and Convention Center** just outside of **Washington, D.C.** This year's theme is "Shaping the Future of

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Mobile Health" and will be explored through a cross-sectoral lens that focuses on the critical areas of Technology, Research, Policy, Business, and mFinance.

This year marks increased interest for the event, with early registrations at an all-time high. There are new exhibitors and sponsors, as well as an impressive list of strategic affiliates for 2011: CDC Foundation, Center for Connected Health, Continua Health Alliance, Edelman (a New York public relations firm), GBCHealth, Association for the Advancement of Medical Instrumentation, Pan American Health Organization, mHealth Regulatory Coalition, Robert Wood Johnson Foundation/Pioneer, The Rockefeller Foundation, United Nations Foundation, Gary & Mary West Wireless Health Institute, and Wireless-Life Sciences Alliance.

The explosive growth of this extraordinary Summit, as well as the need for space to facilitate networking opportunities, necessitated the move to the Gaylord. The larger venue will provide 30,000 square feet of exhibit space, which will include a Qualcomm Pavilion, a Startup Pavilion featuring 40 startup companies (under the auspices of Blueprint Health, Rock Health, and Startup Health), and a new NIH Pavilion being developed to offer maximal exposure and networking opportunities for the agency. Significant increases in attendance are expected, with between 3,500 and 4,500 representatives from 50 countries projected to participate.

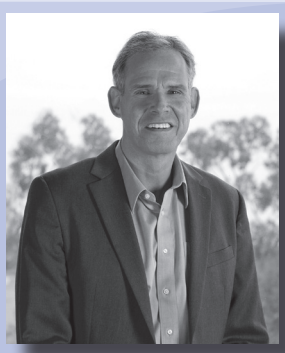
Verizon Wireless will return for a second year as the partnering sponsor and will be joined by other sponsoring companies: Abbott Laboratories, AT&T, Battelle Memorial Institute, CTIS, Inc., Intel Corporation, Johnson & Johnson, McKesson Corporation, Pfizer Inc., Qualcomm, Robert Wood Johnson Foundation, and UnitedHealth Group.

Moving away from the 2010 conference program model, which was dominated by super sessions, this year's expanded program will offer **8 keynote addresses, 4 super sessions,** and **60 concurrent sessions across 12 tracks.** The overall program will be aligned to the five key topic areas of the event: Technology, Research, Policy, Business, and mFinance. The program will prominently feature **15 research sessions** organized under 3 tracks, which are being developed by the NIH, in the areas of Wellness and Prevention, Diagnostics and Assessment, and Acute and Chronic Disease Management.

The speaker lineup is well under way, with Dr. Paul E. Jacobs, Chairman and Chief Executive Officer, Qualcomm; Mr. John Stratton, Executive Vice President and Chief Operating Officer, Verizon Wireless; Ms. Sangita Reddy, Executive Director, Operations, Apollo Hospitals Group; and Dr. Eric J. Topol, Vice Chairman, Gary & Mary West Wireless Health Institute confirmed as keynote speakers. Many more visionary keynote speakers, moderators, and panelists will soon be announced and will showcase NIH leadership throughout the event.

Dr. Paul E. Jacobs

This year, the Summit will feature several co-located events including the M-Enabling Summit focused on mobile and wireless technologies for seniors and persons with disabilities. This event is being produced in conjunction with G3ict (Global Initiative for Inclusive Information and Communication Technologies), Federal Communications Commission, and International Telecommunication Union and will attract several hundred international attendees.



Dr. Eric J. Topol

In conjunction with the 2011 mHealth Summit, the NIH Mobile Health (mHealth) Winter Institute, hosted by the Office of Behavioral and Social Sciences Research, NIH Office of the Director, and many other NIH Institutes and Centers and Federal partners, will take place on December 5-9, 2011, at the Gaylord and has been made possible in part by support from the FNIH.

Attendees at the 2011 Summit will be joining the premier international forum for dialogue, world-class thought leadership, visionary keynotes, and action-provoking panel discussions on mHealth. The Summit will build on previous successes with its robust and comprehensive program agenda, focusing on the technology, research, business, and policy perspectives of mHealth, and will aid in identifying and accelerating sustainable mHealth solutions.

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The FNIH has once again made available a Federal registration rate that offers a significant discount over the normal rate. Visit www.mhealthsummit.org to register today and make sure to follow @mhealthsummit on Twitter. ❖

Open-Source Integrative Informatics: A New Partnership Opportunity

Eric D. Perakslis, Ph.D., Vice President, Research & Development IT, Johnson and Johnson Pharmaceutical Research and Development

Effective translational medicine in biopharmaceutical research and development (R&D) is highly dependent on access to, as well as the availability, integration, and understanding of, many types of data. Done well, the result is the capability to improve decision making when considering complex translational questions:

- What is the correlation between animal models and human data?
- Which patients may benefit from a given compound?
- In which diseases will a compound be effective?
- How can diseases/patients be stratified based on clinical data?
- Is a biological target clinically relevant?

The pharmaceutical companies of Johnson and Johnson (J&J) have established a data warehouse and data-mining application, *tran*SMART, to support translational medicine research and help answer these specific questions. The solution relies heavily on open-source components and was the first enterprise application at J&J hosted on a public cloud. Public cloud hosting offers significant economies over hosting on local or central servers and facilitates participation from multiple locations and parties that might otherwise find such a system out of reach.

The success of the system within J&J led to the study of the system outside of J&J, and the open-source framework has enabled extensive adoption and utility of *tran*SMART by multiple consortia, academic medical centers, and other biopharmaceutical companies. At the present time, there are more than a dozen instances of *tran*SMART around the world being built and used by non-J&J organizations for translational medicine research. Success in using *tran*SMART as the data warehousing and analysis platform for U BIOPRED (Unbiased BIOmarkers in PREDiction of respiratory disease outcomes) project, an industry-academic effort to investigate asthma and asthma treatments that is funded through the European Union's Innovative Medicines Initiative (IMI), has led to its adoption for upcoming IMI initiatives.

J&J is committed to precompetitive data and technology sharing. This is why the *tran*SMART system was built using a backbone of open-source tools (the National Institutes of Health-funded i2b2 Informatics for Integrating Biology and the Bedside, developed the NIH-funded National Center for Biomedical Computing located at Partners HealthCare System at Harvard Medical School) and why J&J has shared the system so freely. It is clear that cross-company and cross-domain team-based science is essential for the data density needed to make meaningful progress against very complex diseases. Only with the sharing of tools and data will the toughest challenges in health care be solved.

The NIH has joined with J&J as an essential partner in this effort. Recently, on April 29, 2011, the NIH Public-Private Partnership Program convened a cross-sectoral consortium design meeting and has catalyzed dialogue that is moving this successful system into new domains, organizations, and directions. In particular, an exciting new collaboration of the University of Michigan, J&J, and One Mind for Research (1Mind4Research.org) was formed at the recent meeting in Bethesda. The result is a new alliance that will construct a precompetitive disease knowledge network focused on posttraumatic stress disorder and traumatic brain injury in returning war fighters. This also provides an opportunity for NIH and NIH-funded investigators to join in this effort and thereby further enhance the sharing of data and insights. ❖

"The NIH has joined with J&J as an essential partner in this effort. Recently, on April 29, 2011, the NIH Public-Private Partnership Program convened a cross-sectoral consortium design meeting and has catalyzed dialogue that is moving this successful system into new domains, organizations, and directions."

Crowdsourcing: The Art and Science of Open Innovation

Olga Brazhnik, Ph.D., Division of Biomedical Technology, National Center for Research Resources

Successful problem solving, in this era of ubiquitous connectivity, can result from millions of people contributing their innovative ideas and unique skills to a solution to a problem. **Crowdsourcing** is the act of outsourcing tasks to an undefined, large community or crowd through an open call. But how can the benefits of crowdsourcing be optimized, and what incentives are needed?

Congress has recently granted broad prize authority to all Federal agencies, and President Obama is encouraging all agencies to use open innovation approaches to accomplish their missions. Examining new ways to incentivize innovation in biomedical research in the context of the new prize authority was the focus of the National Institutes of Health (NIH)-sponsored meeting "Crowdsourcing: The Art and Science of Open Innovation," held on July 18, 2011, in Bethesda, MD. About 300 people attended, and another 350 were able to participate through remote real-time viewing.

Crowdsourcing and Prizes

Prizes have been used throughout history to motivate technological breakthrough. One example was the $25,000 prize offered on May 19, 1919, by New York hotel owner Raymond Orteig to the first aviator to fly nonstop from New York City to Paris, France, or vice-versa. For 5 years, the offer attracted no competitors. It was renewed in 1924. The state of aviation technology had advanced by then, and several famous aviators made unsuccessful attempts before 25-year-old U.S. Air Mail pilot Charles Lindbergh completed his solo nonstop flight from New York City to Paris in 1927. This example illustrates a number of important concepts. First of all, a prize provides a *cost-efficient approach*, as it is only awarded when results are delivered. Second, it enables the participation of young people and people with diverse educational backgrounds, as it is *based on the actual results and not on credentials*. Third, the prize can be offered when the technology is *almost there*, motivating the push to reach the goal. The Orteig Prize also showed how different domains of human activity can advance and benefit from each other. In this case, the motivation for the prize was the expected increase in hotel revenues once intercontinental air travel would be possible, thereby driving technology development.

Don't do it alone!

Main Questions of Crowdsourcing

Speakers at the July meeting addressed key questions about crowdsourcing through plenary presentations and panel discussions. The first key question discussed was:

What does it mean to make innovation a natural part of life?

Tim O'Reilly, Founder and Chief Executive Officer of O'Reilly Media, Inc., provided his perspectives on fostering the culture of sustainable innovation. Using the example of the World Wide Web (WWW), Mr. O'Reilly noted that creating innovative architectures of participation can enable outcomes not envisioned by their creators. The WWW was distinguished from other, similar systems then in use by designing an architecture usable by anyone, no invitations needed. The creators of the WWW simply said, "Here it is; use it." Simple rules for communication and engagement were key success factors. Effective systems are simple and may create unintended consequences. Simple systems also assume the possibility for failure. In embracing innovation, we should not be afraid to fail.

He also discussed explicit and implicit crowdsourcing (an open call to solve a defined problem vs. collecting data and making them openly available). It is great to invite people to work toward a common goal, but what if the goal is wrong? Using open data enables us to take advantage of the collective intelligence and correct our course more easily.

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Dr. Karim Lakhani: "Reviewers should focus on solution rather than the person making the proposal."

Mr. O'Reilly emphasized that the Internet is changing how research is done. For example, the Google autonomous vehicle learned to drive based on data collected for Google Street View, then artificial intelligence was applied to these massive data. Web sites like Quantified Self Labs (www.quantifiedself.com) and PatientsLikeMe (www.patientslikeme.com) gather more clinical and patient data than any existing research studies. New data mean new kinds of research and the ability to develop multiple hypotheses from such data, thus complementing traditional approaches to academic research.

A second question, addressed by a leading academic expert on the topics of crowdsourcing and open innovation, Karim R. Lakhani, Ph.D., of Harvard Business School, was:

How to access the ideas that exist out there? How to access the idea cloud?

Since "most of the smartest people work for someone else" ("Joe's law") and knowledge is unevenly distributed in society, achieving a wide participation that provides a sufficient quantity and variety of ideas is critical to successful innovation. Both competition and collaboration help increase the variety and volume of outcomes.

It is interesting that the motives for participation are not limited to monetary rewards such as prizes; they include a sense of creativity, fun, skill building, increasing knowledge, and identification with a community. Dr. Lakhani also noted that women, although participating less frequently than men, often outperform men in problem-solving.

He recounted a classic case in problem-solving regarding the need to find longitude when at sea. The British Parliament established a Longitude Prize, invited solutions, and established an administrative board. Isaac Newton was on the administrative board and encouraged contestants to concentrate on astronomy for a solution—a form of bias known as a local search. The successful answer, achieved 25 years later, featured the development of a chronometer, or accurate clock.

The longitude example may be relevant to NIH as a crowdsourcing organization using open competitions for investigator-initiated grants. Bias in review may incline toward supporting the status quo and known solvers, and Dr. Lakhani suggested that reviewers focus on the solution rather than on the person making the proposal, stating that we need to lower the barriers to entry by solvers.

The Spectrum of Open Innovation was the focus of a panel, asking:

What does innovation enable us to achieve that we cannot achieve otherwise?

Examples presented by panelists included:

- The National Aeronautics and Space Administration (NASA) launched a prize for a forecasting algorithm to protect U.S. astronauts from radiation exposure in space. Over 500 problem-solvers from 53 countries answered NASA's call. Although NASA's expectations for a solution to this long-intractable problem were low, a solution that exceeded their requirements was submitted by a retired radiofrequency engineer in rural New Hampshire. The winner had never before responded to a government request for proposals, let alone worked with NASA, yet his winning approach forecast solar proton events with 85% accuracy, a result NASA dubbed "outstanding."
- TopCoder, Inc., conducted a competition on the development of a tool for calculating the edit distance between a query deoxyribonucleic acid (DNA) string and an original DNA string. The winning solution performed 120 times faster than a standard MegaBlast program.
- An amyotrophic lateral sclerosis (Lou Gehrig's disease) biomarker with a proven value has been identified and incorporated into a Phase III clinical trial as a result of a Prize4Life, Inc., competition.

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- Twelve pioneering ideas for attacking type 1 diabetes were selected through a crowdsourcing experiment in which all members of the Harvard community and the general public were invited to answer the question: What do we not know about curing type 1 diabetes? Winning submissions were from diverse members of the Harvard community, including an undergraduate chemistry student. With funding from a donor, projects are under way to assess whether any of the novel approaches are clinically useful.

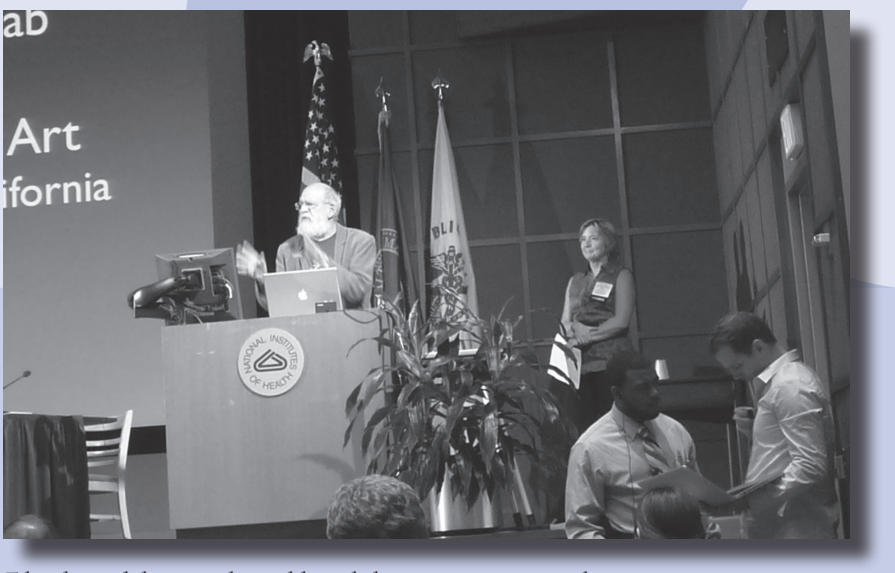
According to InnoCentive, Inc., President Dwayne Spradlin, offering prizes has several advantages over granting or sponsoring research, as funders get many fresh looks at the problem for less money than it usually costs to provide a grant. This process also distributes risk and accelerates research. "In our world, challenges are fundamental because they are units of problem-solving. In the 21st century, if we define problems correctly and package them appropriately, we can then push them out to the rest of the world. It's vital to frame the problems correctly," emphasized Mr. Spradlin. "If there is a problem that can be defined well and distributed, we can engage the entire world in this process of solving it. InnoCentive challenges reach 12+ million potential problem-solvers… and that number is growing!"

The panelists brought to light the importance of engaging nontraditional communities, well-framed questions, implementation of an objective screening process, clear and open evaluation criteria, and the necessary feedback to the participants that builds a sense of community and may reduce the burnout effect.

Jeremy Kagan, an internationally recognized and award-winning director, writer, and producer of feature films and television and professor at the University of Southern California, noted a film's ability to go beyond knowledge in motivating people as a means of addressing the question:

How do we engage communities of solvers?

Clear and simple communication has been named a critical factor in crowdsourcing. What does clear and simple communication mean? If we read that 1,500 people die each day in the United States due to cancer, how does it make us act? Does it motivate us to change our behaviors? How? Or, in seeking a solution to a specific scientific problem, even if we can explain what it is that we are looking for, how do we convince people to consider the task to be important, interesting, worthy of their time, and relevant to their lives? The art of crowdsourcing requires us to make people act and to motivate the crowds. Fortunately, there are industries that have been studying and developing these techniques for ages. We all know how a good movie can make us cry or laugh or make us sentimental or angry. Cinema gurus use special tricks and techniques, special approaches to reach our hearts, to make us aware of a problem and to engage us in its solution.



Films have ability to go beyond knowledge in motivating people.

Professor Kagan discussed two versions of a film encouraging women to obtain Pap tests in discussion of the fact that, even when people know how to prevent a disease, they often won't do it. The film, produced as part of a comparative effectiveness study funded by the National Cancer Institute (NCI) at USC's Change Making Media Lab and created by Professor Kagan, investigates the internal elements of cinema for behavioral effectiveness. He is currently working with the USC Medical School on using a combination of entertainment and education to deal with obesity in middle-school kids. Professor Kagan explained that storytelling tends to produce greater motivation for the viewer to make changes than a fact-based documentary. When a moviegoer identifies with a film character's experiences, it creates a feeling in the moviegoer that he or she could be that character. Facts tell, stories sell, he added.

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Professor Kagan demonstrated a few amazing projects, enabled by universal access to the Internet, where people play music, sing, or create animation together while separated by miles and oceans. He contrasted this with the hierarchy of movie production, to which everyone contributes, but the decision is made by the final authority. (This model is well known from *The Wisdom of Crowds* by James Surowiecki.)

Another way to engage crowds in solving problems is to let them have fun. The principles of using collective intelligence in science were showcased in a spectacular presentation from the co-creator of online games FoldIt (protein folding) and EteRNA (nanoengineering), Adrien Treuille, Ph.D., Carnegie Mellon University. In Foldit, launched in 2008, 57,000 players compete against a computer in solving one of the greatest challenges in biology (i.e., creating protein structures based on the known sequences). In EteRNA, launched in 2011, 25,000 players compete against nature directly through experiments to design real molecules. Here, the task is to design a ribonucleic acid (RNA) molecule that folds naturally into a predefined shape. Players vote weekly on the best designs, which are then synthesized in a lab, testing the predicted structure against the actual structure, thus crowdsourcing the entire scientific method from hypothesis to experimental results. Designing the problem as a game created a lot of unanticipated consequences. The players changed the problem. The real scientists loved the intuitive visual interfaces that were designed from the perspective of a child, and Foldit is now used by graduate students and postdocs in biochemistry labs to design protein and protein interfaces. A pharmaceutical company wants to use its interface on its Web site so customers may see what they are ordering. By marrying modern human-computer interaction and user interface techniques with biological processes, a new field of interactive biology is created. Dr. Treuille demonstrated several examples in which humans could solve hard problems, those that computers could not solve because many models currently used in computations are wrong. Humans learn quickly and create knowledge whereas computers do not. A huge advantage is that computers work for free! There are many reasons for humans' abilities to solve such problems, including the subtle connection to science, the beauty of molecules, the opportunity to measure their skills against something, and the chance to use abilities they didn't know they had. The fun of working with 57,000 people is like having the biggest party in the world, Dr. Treuille said.

A published paper about Foldit included the citing of "all the players" in the list of authors, which gave it the distinction of having the most authors of any paper. His innovative approaches to science made Dr. Treuille one of the top 35 innovators under the age of 35 named by the Massachusetts Institute of Technology's *Technology Review* magazine.

The panel titled "Do Not Do It Alone!!" addressed the question:

What resources exist out there to support our exploration of open-innovation approaches?

The panel included representatives of the White House Office of Science and Technology Policy (OSTP), U.S. Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology, Health 2.0, and OmniCompete, as well as the NIH. The panelists spelled out in detail the support and encouragement from the White House and HHS and the expertise offered by the private sector. The panelists encouraged novices to open-innovation approaches to create a vision beyond the challenge, see the big picture, explore unusual places and partners, and create communities. "Once you link with the community, phenomenal things happen," said Aman Bhandari, HHS.

Todd Park: "The Art and Science of Open Innovation is my favorite topic in the entire world."

Enthusiastic HHS support also came from Todd Park, HHS Chief Technology Officer. He emphasized that President Obama had made innovation a top priority of his administration and that the topic is of high relevance beyond the biomedical research community. Mr. Park discussed the HHS Community Health Data Initiative that started with the production of easily accessible administrative, public health, and research data, which fueled the innovation of new applications. However, it did not happen just as a consequence of making the data available. Leveraging the

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Discussions

capabilities of the WWW, they used social networking platforms, mobile technologies, and other resources to improve the liquidity of data and promote creative applications of them to benefit the health and health care of the public. The use of crowdsourcing methods, challenges, and code-a-thons were important catalysts that provided unprecedented means to reach unique talents and expertise to work on some of our most vexing problems. "The art and science of open innovation is my favorite topic in the entire world," Mr. Park said.

The EXPO that ran throughout the day provided opportunities for meeting new partners and learning more about successful projects and existing resources.

In his closing remarks, James Anderson, M.D., Ph.D., Director, NIH Division of Program Coordination, Planning, and Strategic Initiatives, NIH Office of the Director, explained that the NIH is working on developing policies for NIH uses of prizes and challenges to meet the NIH mission.

Discussions continued throughout the evening and the next day, which allowed NIH open-innovation enthusiasts to have detailed discussions with experts while focusing on the NIH-specific environment.

The Sequel

An African proverb states, "If you want to go faster, go alone. If you want to go further, go together." The era of ubiquitous connectivity advances this idea to a new level. Bringing the power of collective intelligence to fruition, tapping the global mind, and finding the most extraordinary approaches to solving important problems require new skills and new partners.

The meeting started a conversation among many interested parties; the next day, *Science* published an article about the meeting (http://news.sciencemag.org/scienceinsider/2011/07/will-nih-embrace-biomedical-research.html?ref=hp).

I hope you will learn a lot of new concepts and have fun watching the videocast of the event (http://videocast.nih.gov/summary.asp?Live=10366).

I would like to express my deepest gratitude to the many people who made this event happen. I am forever grateful to Barbara Alving, M.D., Director, National Center for Research Resources, and Robynn Sturm, J.D., OSTP, for their support and inspiration. I would like to express my gratitude to the members of the organizing committee who shared this exciting and bumpy journey with me: Abdul Shaikh, Ph.D., NCI; Jennifer Couch, Ph.D., NCI; John Haller, Ph.D., National Institute of Biomedical Imaging and Bioengineering; Tisha Wiley, Ph.D., OD; Peter Lyster, Ph.D., National Institute of General Medical Sciences; Elena Koustova, Ph.D., M.B.A., National Institute on Drug Abuse; and Barbara B. Mittleman, M.D., Director, Public-Private Partnership Program, Office of Science Policy Analysis, Office of Science Policy, Office of the Director. And I would like to thank everyone who emailed me to say that the meeting was AWESOME!

Let's go together. ❖

Public-Private Partnerships at the Forefront of Public Health and Economic Development

Agnes B. Rooke, J.D., M.S., Technology Development and Transfer Associate, Inventions and Agreements Branch, Office of Technology Development, National Institute of Allergy and Infectious Diseases

Importance of the NIH Public-Private Partnerships in Facilitating the Progress of Public Health Research

The National Institutes of Health (NIH) Public-Private Partnership (PPP) Program was designated to facilitate collaborations that improve public health through biomedical research. The PPP Program serves as a point of contact and resource for entities interested in partnering with the NIH and provides the necessary guidance for the initiation, establishment, and implementation of new PPPs through innovative arrangements that address important public health issues.

The NIH PPP Program staff engages with a wide range of entities, including academia, nongovernmental organizations, not-for-profit organizations, patient advocacy groups, government and intergovernmental agencies, professional societies, and charitable foundations as well as members of the private sector, including pharmaceutical and biotech companies.

The principal function of the NIH PPP Program is to bring together a variety of sectors that share common goals, including the advancement of biomedical science, public health, and the facilitation of collaborations that foster pharmaceutical innovation. Those collaborations pave the way for a new generation of medicines that can ultimately save and improve lives and offer new cures. Thus, the NIH PPP Program has a unique opportunity to serve as a catalyst for the promotion of public health to be addressed in all sectors of scientific research.

A PPP is an agreement between government and nongovernment entities in which each partner shares in the potential risks and rewards of the formed partnership. PPPs represent a great vehicle for the Federal government to address complex public health challenges and, in particular, to unite other Federal agencies and nongovernment entities around a common problem to spur collaboration for the public good. When managed with a clear understanding of public and private sector concerns, PPPs can effectively address unmet public health needs and critical public health objectives.

PPP participants from the private sector can contribute methodological knowledge, financial and in-kind resources, and commercialization and marketing expertise, whereas the public sector and academia generally provide scientific research know-how and new discoveries, coupled with institutional and infrastructural support.

By entering into PPPs, new technologies developed in government or academic laboratories may be further utilized and commercialized by the private sector, and potential new drugs are developed faster. PPPs can play an important role in transferring new medicines from "bench to bedside" by accelerating the translation of basic research into clinical applications and accelerating patient access to innovative treatments.

How To Set Up Successful PPPs: Recent Examples

In 2011 the NIH PPP Program assisted with and provided advisory guidance in the organization of two groundbreaking workshops: the *tran*SMART Consortium Workshop and the Federal Biovigilance Partners Workshop, both of which have a significant potential for impact on the public health.

The *tran*SMART Consortium Workshop included the participation of several Federal agencies, as well as several nonprofit entities, academic institutions, and companies, for the purpose of introducing the translational medicine data warehouse to the research community. Under this partnership, Johnson & Johnson would provide an open-source knowledge management platform hosted on Amazon's public cloud computing server for a variety of research and R&D (research and development) uses. Recently, the same system was adopted by the Innovative Medicines Initiative, a program launched by the European Commission and the European Federation of Pharmaceutical Industries and Associations to sponsor collaborative research among major drug companies. Furthermore, the partnership could provide a secure, open-source, low-cost, and high-quality technology infrastructure for industry, academia, and government and nongovernment organizations. This infrastructure would facilitate the sharing of data resources and would enable advanced translational knowledge management both within participating partner organizations and/or collaboratively via a hosted framework. The shared data may include clinical trial data, drug targets,

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gene expression, protein profiling, curated text, text indexing, vocabularies, and metadata developed in industry and academia as well as any appropriate Federal data resources.

The Federal Biovigilance Partners Workshop was initiated by U.S Department of Health and Human Services' Assistant Secretary for Health, Dr. Howard Koh, to promote greater safety and appropriate health outcomes for donors and recipients of blood, tissues, and organs at the national level, with the eventual goal of establishing a PPP. This groundbreaking workshop addressed not just the broad mission of biovigilance as it relates to public health but also the individual interests, visions, and agendas of each participating Federal agency. The participants included representatives from the NIH, U.S. Food and Drug Administration, Centers for Disease Control and Prevention, Office of the Assistant Secretary for Health, Health Resources and Services Administration, Centers for Medicare & Medicaid Services, U.S. Department of Veterans Affairs, Agency for Healthcare Research and Quality, U.S. Department of Defense, and others. The main points of discussion involved the current status of biovigilance efforts across agencies with the main objectives of (1) identifying a shared Federal vision for a national biovigilance program that includes participation from the public and private sectors and the creation and maintenance of a collaborative structure between them; (2) implementing metrics for reporting data and establishing databases to improve patient safety; (3) implementing data collection, analysis, and reporting trends for adverse events; (4) establishing common standards and definitions for monitoring, measuring, and reporting results and adverse effects; (5) establishing effective communication among Federal agencies and identifying the most productive ways for agencies to work together; and (6) identifying next steps, options, and strategies for future engagements with other Federal and non-Federal partners.

Effective Structuring of Successful PPPs

The diverse examples described above give a hint that there is no single template agreement that applies to formation of all PPPs. Collaborations should be considered individually and should draw on the uniqueness and strengths of each participating partner. Each partnership commences by identifying a public health need or scientific opportunity that engaging diverse partners can provide the means to solve or address.

Before entering into a PPP, all potential partners should examine the following questions: (1) Why is the partnership being formed? (2) Who are the appropriate partners, and what are their specific roles? (3) What are the goals of the partnership? (4) How should the partnership be established? (5) How will the partnership meet its objectives? (6) When should the partnership be established? and (7) What are the benefits and commitments in entering into the PPP?

After the agenda and goals of the PPP are clarified, each partner should focus on the specific issues to be defined in the partnership agreement, such as (1) the scope and nature of the partnership; (2) the roles and responsibilities of the partners and stakeholders; (3) the governance and management of the partnership and designation of the managing partner; (4) management of confidentiality and conflict-of-interest; (5) how risk, liability, and change of control will be addressed; (6) who can indemnify whom; (7) intellectual property (IP) and data protection; (8) outputs and deliverables; (9) exit routes; (10) other agreements (e.g., memoranda of understanding, IP licenses, assignments); (11) financial contributions and financial strategy to sustain the partnership; (12) warranties; (13) IP ownership (i.e., single ownership, joint ownership of all partners, or no ownership); (14) background IP (i.e., who has the authority to use it, assignment or license to a partner to use it, or royalty payments to the partner owning background IP in exchange for remaining partners to use it); (15) data management, including collection, maintenance, protection, monitoring, security, and exploitation; and (16) handling of IP and data after termination of the PPP. When the Federal government is a partner in a PPP, all terms and conditions must comply with Federal laws, regulations, and policies in order for the government to be able to participate. (It may happen that Federal participants follow one set of rules while other partners follow other rules, in order for the government to participate and for the PPP to meet its objectives.)

Moreover, individual interests, expectations, and goals must be clear to all partners entering into a PPP, and its success must be continuously encouraged through oversight during the duration of the collaboration. Effective partnerships are founded on mutual need, trust, effective exchange of information, and understanding of the value added to all partners.

Effective Management of PPPs Through the Lens of IP and Technology Transfer

Knowledge of technology transfer laws, policies, and regulations is imperative to the effective formation and governance of PPPs. In addition, one must possess the ability to draft legal documents that effectively address the

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governance, goals, and objectives of PPPs and to evaluate the pros and cons of data ownership and sharing of IP. Moreover, knowledge of how to protect IP (e.g., patents, trademarks, copyrights, trade secrets, know-how) is also necessary, since in some PPPs there is a high probability that IP will be created or conceived during the duration of the partnership. In addition, understanding of IP law in the context of PPPs is crucial because patents create an incentive for determining who can or cannot participate in a given PPP.

Within a PPP there needs to be a reasonable balance between free exchange of the information and the need of collaborating partners to safeguard their own pre-existing IP as well as partnership-developed IP for potential commercialization and further development. Thus, IP-related decisions should be weighed very carefully, since patenting could delay the release of important information and thus impede scientific innovation and exchange of results between the collaborators.

To patent or not to patent, that is the question, and each partner should decide early on how patenting issues will be addressed in the context of the PPP. Several questions are critical: (1) Is patenting of inventions necessary to further the goals of the PPP? (2) Is strategic patenting by pursuing patents only for certain technologies or only in certain regions of the world supportive of the goals of the PPP? and (3) Will releasing all data into the public domain and not patenting at all advance the PPP's agenda and public health mission?

Furthermore, ownership and control of inventions created during the PPP's project can be managed strategically, depending on the specific needs of the PPP, for example: (1) generating precompetitive resources with no IP protection; (2) joint ownership of inventions by all members of the PPP; or (3) shared use of IP with partners that have ownership rights in IP generated during the PPP's project would grant to all remaining partners a nonexclusive and remuneration-free license.

Thus, IP management should take into account the particular PPP's structure and objectives as well as background IP already owned by members entering into the partnership. Which strategy fits best will depend on the particular situation and goals of the PPP; however, NIH always favors an open access and precompetitive approach whenever possible.

Moreover, a data-sharing policy should be articulated early in the discussion of PPP formation. PPP members should establish data-sharing relationships by (1) specifying how samples and primary data will be transferred; (2) specifying how data will be analyzed; (3) determining how the results of analysis will be released into the public domain; and (3) deciding when to release data in case IP protection is sought (i.e., once research findings are published, they cannot be patented in most countries, although in the United States there is a 1-year period for filing patent application after the invention is disclosed.)

The IP and data-sharing policy must be clear and transparent, but at the same time flexible and adaptable to minimize the effects of unexpected circumstances (e.g., bringing new members into the established PPP, addressing different forms of IP).

Effect of PPPs on Economic Development and Job Creation

Economic benefits arising from PPPs include innovations of new products, translation of basic research into new lifesaving treatments, new pharmaceuticals, and creation of potential new infrastructures and markets for economic growth and development of a particular research area.

Typically, PPPs draw on the industry's in-depth expertise in technology management, product development, and process of effectively disseminating new pharmaceuticals for public use. PPPs can bridge the gap between basic research and drug development by connecting government investment in basic and early-stage research with the development, regulatory, and marketing power of industry, thus effecting translation of discovery to products that can lead to improvements in public health. The public sector, academia, and nonprofits can also benefit in the short term from partnering with the private sector by (1) accessing funding from private entities, (2) expanding their research capabilities, (3) acquiring access to methodological knowledge and tools, (4) acquiring marketing expertise, and (5) gaining the ability to explore new research opportunities.

In addition, society as a whole benefits from PPPs in the following ways: (1) research results can be validated faster and more economically because duplication of effort is avoided; (2) efficiencies in traversing regulatory stage-gates can be achieved through the availability of shared and validated tools and metrics; (3) access to innovative research and expertise available in the public and private sectors is made possible; (4) access to diverse points of view is gained; (5) there can be a focus on areas of research that are underdeveloped or underrepresented; (6) there is faster progress of data generation, collection, and analysis thus speeding the time needed to approve and commercialize new drugs; and (7) faster commercialization and generation of additional interest in particular areas of research are possible due to the exchange of expertise across geographic locations, cultures, backgrounds, and unique projects.

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Visit us at **http://ppp.od.nih.gov**

LOOKING FOR PPP INFORMATION?

Program on Public-Private Partnerships
Office of Science Policy Analysis
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1, Room 209
1 Center Drive, MSC 0170
Bethesda, Maryland 20892

301.443.YPPP (9777)
301.480.1147 fax
pppartnerships@od.nih.gov

Please send your ideas and comments for future *PPP Advisor* articles/ publications to:

Marjorie Bonorden, Editor
PPP Program
Building 1, Room 209
Bethesda, Maryland 20892
or email: bonordenm@od.nih.gov

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Thus, PPPs have the potential to stimulate the current economy and help create jobs by linking government/public capabilities with those of the private sector, leading to more research and the translation of research to the public through developing, marketing, manufacturing, and distributing products from newly created technologies. Through PPPs, the private sector can invest in new health care technologies, commercialize promising innovations, create new research tools that target diseases, and implement new medical treatments faster.

Conclusion

The formation of PPPs presents a win-win situation for both the Federal government and the private sector because both entities can effectively collaborate, pool their critical thinking, and utilize current knowledge, expertise, and resources to improve the health of U.S. citizens and the rest of the world more quickly and efficiently. Through PPPs, new ideas are born, and new inventions are implemented.

The NIH PPP Program consists of people who are passionate ambassadors for the public health mission. The office plays a pivotal role in bringing key players together, and its existence and contributions are a true asset to the NIH mission, which is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce burdens of illness and disability." The NIH PPP Program clearly exemplifies this ethos. ❖

Calendar

Date	Meeting	Location & Time
10.20.11	PPP Coordinating Committee Meeting*	NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm
10.25.11	mHealth IIIG Meeting**	NIH Campus, Building 31, Room 6C7, 3:00 - 4:30 pm
11.17.11	PPP Coordinating Committee Meeting*	NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm
12.5.11-12.9.11	2011 mHealth Summit	Gaylord Resort & Convention Center, Washington, DC
12.7.11-12.9.11	mHealth Winter Institute at the 2011 mHealth Summit	Gaylord Resort & Convention Center, Washington, DC
12.15.11	PPP Coordinating Committee Meeting*	NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm
12.20.11	mHealth IIIG Meeting**	NIH Campus, Building 31, Room 6C7, 3:00 - 4:30 pm

*The PPP Coordinating Committee (PPPCC) meets on the third Thursday of each month. For additional information, please contact Ms. Marjorie Bonorden at bonordenm@od.nih.gov.

**mHealth IIIG Committee. For additional information about the committee or the meetings, please contact Dr. Bill Riley at william.riley@nih.gov.

All meeting locations are subject to change.

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